EXHIBIT C

Form Approved Through 05/2004
OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

# Grant Application

*Follow instructions carefully.*
*Do not exceed 56-character length restrictions, including spaces.*

**LEAVE BLANK—FOR PHS USE ONLY.**

| Type | Activity | Number |
|---|---|---|
| Review Group | | Formerly |
| Council/Board (Month, Year) | | Date Received |

1. TITLE OF PROJECT

Development of a Massed Practice Stroke Therapy Device

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
*(If "Yes," state number and title)*
Number: PHS 2002-2 Title: SBIR

**3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR**

**New Investigator** ☒ No ☐ Yes

3a. NAME *(Last, first, middle)*
Koeneman, James, Bryant

3b. DEGREE(S)
BSME MS PhD

3c. POSITION TITLE
President

3d. MAILING ADDRESS *(Street, city, state, zip code)*
1949 East Broadway Road, Suite D
Tempe, AZ 85282

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

3f. MAJOR SUBDIVISION

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL (480)557-0448 FAX: (480) 557-0449

E-MAIL ADDRESS:
jkoeneman@kineticmuscles.com

| 4. HUMAN SUBJECTS RESEARCH | 4a. Research Exempt ☒ No ☐ Yes If "Yes," Exemption No. | 5. VERTEBRATE ANIMALS ☒ No ☐ Yes | |
|---|---|---|---|
| ☐ No ☒ Yes | 4b. Human Subjects Assurance No. None | 4c. NIH-defined Phase III Clinical Trial ☒ No ☐ Yes | 5a. If "Yes," IACUC approval Date / 5b. Animal welfare assurance no |

| 6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)* | | 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD | 8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT | |
|---|---|---|---|---|
| From | Through | 7a. Direct Costs ($) | 8a. Direct Costs ($) | 8b. Total Costs ($) |
| 04/01/03 | 09/30/03 | $100,000 | $100,000 | $100,000 |

9. APPLICANT ORGANIZATION
Name: Kinetic Muscles, Inc.
Address: 1949 East Broadway Road, Suite D
Tempe, AZ 85282

Institutional Profile File Number (if known)

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☐ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☒ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
EIN 86-1031432
DUNS NO *(If available)*

Congressional District: 1

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name: Jame B. Koeneman
Title: President
Address: 1949 East Broadway Road
Tempe, AZ 85282

Tel: (480) 557-0448 FAX: (480) 55-0449
E-Mail: jkoeneman@kineticmuslces.com

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name: James B. Koeneman
Title: President
Address: 1949 East Broadway Road
Tempe, AZ 85282

Tel: (480) 557-0448 FAX: (480) 557-0449
E-Mail: jkoeneman@kineticmuscles.com

14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 3a. *(In ink. "Per" signature not acceptable.)* — DATE: 7/25/02

15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)* — DATE: 7/29/02

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

Stroke (CVA) is the leading cause of disability in the United States and it is estimated that its prevalence will more than double over the next 50 years. Current stroke therapy is labor-intensive and costly. The United States spends $17 billion taking care of stroke survivors. Recently, concentrated, massed practice therapies have been developed that improve function in CVA patients by reversing the effects of "learned nonuse". The objective of this project is to investigate the feasibility of a device that facilitates the administration of massed practice stroke therapy. The long-term objective is to provide a lightweight device for home use that provides motion and biofeedback of desired and undesireable muscle activity. Software controls the function of the device and monitors patient progress and compliance. A pneumatic artificial muscle will be used to provide physical motion. This artificial muscle has many of the properties of human muscle. It is lightweight, flexible and has spring like properties. This project will focuses on treating wrist and finger extensor weakness, however, the concept applies to all areas affected by motor impairment. This Phase I study includes detailed design verification measurements on the device and measures the responses of able bodied test subjects to the treatment protocol.

PERFORMANCE SITE(S) *(organization, city, state)*
Kinetic Muscles, Inc. Tempe, AZ
Barrow Neurological Institute at St. Joeseph's Hospital and Medical Center, Phoenix, AZ

KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

| Name | Organization | Role on Project |
|---|---|---|
| Koeneman, James B. | Kinetic Muscles, Inc. | P.I. |
| Eblen, Cristobel | Southwest Behavioral Health Center | Statistical Consultant |
| Herring, Donald | Arizona State University | Human Factors, Indus Des. |
| Koeneman, Edward | Kinestic Muscles, Inc. | Device design & fabrication |
| Kwasnica, Christina | Barrows Neurological Institue | Physician evaluation |
| Wendelboe, Douglas | Kinetic Muscles, Inc. | Software & firmware design |
| Wolf, Steven | Emory University | Therapy consultant |

*Disclosure Permission Statement.* Applicable to SBIR/STTR Only. See instructions. ☒ **Yes** ☐ **No**

EXHIBIT C

Principal Investigator/Program Director (Last, First, Middle): Koeneman, James, Bryant

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

## RESEARCH GRANT

## TABLE OF CONTENTS

Principal Investigator/Program Director *(Last, first, middle)*: Koeneman, James, Bryant

| BUDGET JUSTIFICATION PAGE<br>MODULAR RESEARCH GRANT APPLICATION | | | | |
|---|---|---|---|---|
| Initial Budget Period | Second Year of Support | Third Year of Support | Fourth Year of Support | Fifth Year of Support |
| $ 100,000.00 | $ | $ | $ | $ |
| **Total Direct Costs Requested for Entire Project Period** | | | | $ 100,000.00 |

**Personnel**

During the 6 months of this project, the P.I. will have 30% effort. He will coordinate activities, manage the budget and provide biomechanical analysis. Edward Koeneman will have 30% effort during the 6 months. He will be responsible for hardware design, test and assembly of the devices to be used in the pilot study. Douglas Wendelboe will have 30% effort during the 6 months of the project and will be responsible for programming and data retrieval.

**Consortium**

Dr. Kwasnica will assist in selecting the clinical participants in the pilot study and participate in the performance and evaluation of the results of the pilot study. Payment to the clinician and caregiver pilot study participants is budgeted to be $14,000. The statistical consulting of Dr. Eblen plus the Human Factors consulting of Donald Herring and Dr. Kwasnica's consulting are estimated to be $10,000. Dr. Steven Wolf from Emory University will consult on concentrated practice, therapy protocols, and evaluation of results at no cost to the grant.

**Fixed Fee (SBIR/STTR Only)**
None

# BIOGRAPHICAL SKETCH

| NAME | POSITION TITLE |
|---|---|
| James B. Koeneman | Senior Biomechanics Consultant |

EDUCATION (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| University of Minnesota, Minneapolis, MN | BSME | 1959 | Mechanical Engineering |
| Case Western Reserve University, Cleveland, OH | MS | 1966 | Bioengineering |
| Case Western Reserve University, Cleveland, OH | PhD | 1970 | Structures/Mechanical Design |

RESEARCH AND PROFESSIONAL EXPERIENCE

| | |
|---|---|
| 1994 - present | Senior Bioengineering Consultant, BTI Consultants, Tempe, AZ. Assistive Devices, Biomechanics, Development of Composite Materials, Stress Analysis, Failure Analysis. |
| 1994 - 1998 | V.P. of Engineering, Orthologic Corporation, Tempe, AZ. Fracture fixation devices, bone growth stimulators. |
| 1984 - 1994 | Head of Bioengineering Division, Harrington Arthritis Research Center, Phoenix, AZ. Development of assistive devices, orthopedic implant design and testing, finite element analyses. |
| 1981 - 1983 | President, Paulson Medical Devices, Inc., Erie, PA. Development of fracture fixation devices and orthopedic implants. |
| 1974 - 1981 | Head of Bioengineering Division, Lord Corporation, Erie, PA. Development and manufacture of orthopedic implants. Composite material development. |
| 1970 - 1974 | Bell Telephone Laboratories, Columbus, OH. Development of Piezoelectric switching devices. |
| 1960 - 1964 | Reactor Engineer, U.S. Atomic Energy Commission, Argonne, IL. |
| 1959 - 1960 | Reactor Engineer, Argonne National Laboratory, Idaho Falls, ID. |

PUBLICATIONS

Recipient of 16 patents, co-author of 22 publications and over 115 presentations at technical society meetings. Seven relevant publications listed below:

J.B. Koeneman and J.S. Kaiser, "A Functional Evaluation of the DataHand® Key Entry System User Experience Evaluated By Questionnaire," RESNA, 1994.

J.B. Koeneman and C. Eblen, "A Longitudinal Evaluation of Four-Wheeled Walker: Effects of Experience," Topics in Geriatric Rehabilitation, 8(3)3, 1993.

J.B. Koeneman, "Advanced Materials for Assistive Devices," Topics in Geriatric Rehabilitation, Vol. 8, No. 2, December 1992.

J.B. Koeneman, with others, "A Multi-Dimensional Evaluation of a Four-Wheeled Walker," Assistive Technology, Vol. 4, No. 1, 1992.

J.B. Koeneman, N. Reich, P. Otten, and J. Kaiser, "Clothing for Special Needs; An Information Arena," 10th Annual RESNA Conference, San Jose, CA, 1987.

J.B. Koeneman and M. Phillips, "Composite Materials for Rehabilitation Devices," 10th Annual RESNA Conference, San Jose, CA, 1987.

J.B. Koeneman, "State of the Art of Finite Element Analysis in Orthopaedics," Materials Research Society, Proceedings of Medical Devices and Materials Symposium, 1987.

AWARDS

International Fellow of Biomaterials Science and Engineering; International Union of Societies for Biomaterials Science and Engineering (1999)

Clemson Award for Contributions to the Literature, Society for Biomaterials (1997)

Fellow of Society for Advancement of Material and Process Engineering International (SAMPE) (1992)

Chapter Fellow Award, Society for Advancement of Materials and Process Engineering (SAMPE) (1990)

Engineer of the Year Award, Erie Engineering Society Council (1982)

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

| NAME | POSITION TITLE |
|---|---|
| Steven L. Wolf, Ph.D., FAPTA | Professor |

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

| INSTITUTION AND LOCATION | DEGREE (*if applicable*) | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Clark University, Worcester, MA | BA | 1965 | Biology |
| Boston University, Boston, MA | MS | 1969 | Physical Therapy |
| Emory University, Atlanta, GA | MS | 1972 | Anatomy |
| Emory University, Atlanta, GA | PhD | 1973 | Anat/Neurophysiology |
| Karolinska Institute, Stockholm, Sweden | Postdoctoral | 1973-75 | Neurophysiology |

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES.

### RESEARCH AND PROFESSIONAL EXPERIENCE

1969-70 Instructor, Anatomy and Physiology, Boston University, Boston, MA
1975-88 Principal Investigator, Emory University Rehab. Research & Training Center, Atlanta, GA
1975 Assistant Professor, Dept. of Surgery, Emory University School of Medicine, Atlanta, GA
1975-85 Assistant Professor, Dept. Anatomy, Emory University School of Medicine, Atlanta, GA
1975-78 Assistant Professor, Dept. of Rehab. Med., Emory University School of Medicine, Atlanta, GA
1978-85 Associate Professor, Dept. of Rehab Med., Emory University School of Medicine, Atlanta, GA
1985-Present Professor, Dept. of Rehabilitation Medicine, Emory University School of Medicine, Atlanta, GA
1988-2000 Director of Research, Dept. of Rehab. Med., Emory University School of Medicine, Atlanta, GA

### HONORS

Marian Williams Research Award, 1980
Georgia Merit Award, Physical Therapy Association of Georgia, 1983
Golden Pen Award, American Physical Therapy Association, 1983
Catherine Worthingham Fellow of the American Physical Therapy Association, 1987
Outstanding Research Contributor to Advancing the Understanding of Biofeedback Mechanisms, Association of Applied Psychophysiology and Biofeedback, 1987
President, Association of Applied Psychophysiology and Biofeedback, 1991-92
Helen J. Hislop Award for Outstanding Contributions to Professional Literature, American Physical Therapy Association, 1993
Award of Excellence, Section on Clinical Electrophysiology, American Physical Therapy Association, 1993
Steven J. Rose Memorial Lectureship, Washington University, St. Louis, Missouri, 1994
Lucy Blair Service Award, American Physical Therapy Association, 1996
First John V. Basmajian Lectureship, International Society of Electrophysiology and Kinesiology, 1996
Section on Geriatrics, APTA, Outstanding published paper award, 1997.
Neurology Section, APTA, Outstanding Researcher Award, 1998.

Dr. Steve Wolf Appreciation Day, February 11, 1998, Warner-Robbins, Georgia: Outstanding Contributions to Rehabilitation in Georgia.
Lester Duplechen Outstanding Faculty Teacher Award, Department of Rehabilitation Medicine, 1999.
Stroke Council, American Heart Association, 1999.
APTA Mary McMillan Lecturer, 2002

SELECTED RELEVANT PUBLICATIONS (from over 200)

Wolf SL, Catlin PA, Ellis M, et al: Assessing the Wolf motor function test as an outcome measure for research with patients post-stroke. Stroke, 2001, in print.

Sathian K, Greenspan A, Wolf SL: Doing it with mirrors - a novel approach to stroke rehabilitation. J. Neural Repair and Neuroscience,14:73-76, 2000.

Wolf SL, Catlin PA, Ellis M, Link A, Morgan B, Piacentino A: Assessing the Wolf motor function test as an outcome measure for research with patients post-stroke. Stroke, 2000, submitted for publication.

Baer HR, Wolf SL: The modified Emory Functional Ambulation Profile: An outcome measure for the rehabilitation of post-stroke gait dysfunction. Stroke, 32:973-979,2000.

Kressig RW, Wolf SL, Sattin RW, O'Grady M, Greenspan A, Curns A, Kutner M: Associations between demographic and functional characteristics to activity-related fear of falling among older adults transitioning to frailty. J Amer Geriatr Soc, 2001, in print.

Griffith, JS Kreutzer, B Pentland (eds), Rehabilitation of the Adult and Child with Traumatic Brain Injury, third edition, FA Davis, Philadelphia, 2000.

Blanton S, Wolf SL: Effectiveness of upper extremity constraint-induced movement therapy on a patient with sub-acute stroke. Physical Therapy, 79:847-853, 1999.

Wolf SL, Catlin PA, Bonner B, Marks M, Weston M: Up-training loading responses in older adults. Applied Psychophysiology and Biofeedback, 24: 179-195, 1999.

Blanton S, Porter L, Smith D, Wolf SL: Strategies to enhance mobility in traumatic brain injured patients. In M. Rosenthal, ER

Wolf SL, Gregor RJ: Exploring unique applications of kinetic analyses to movement in older adults. J. Applied Biomechanics, 15:75-83, 1999.

Blanton SR, Wolf, SL: Effects of constraint-induced movement therapy intervention on individuals with upper extremity hemiparesis. Neurology Report, 1998, 22:164.

Taub E, Wolf SL: Constraint induction techniques to facilitate upper extremity use in stroke patients. Topics in Stroke Rehabilitation, 4.38-61, 1997.

Edgerton VR, Wolf SL, Levendowski DJ: Theoretical basis for patterning EMG amplitudes to assess muscle dysfunction. Medicine and Science Sports and Exercise, 28:744-751, 1996.

Edgerton VR, Wolf SL, Levendowski DJ, Roy RR: Evaluating patterns of EMG amplitudes for trunk and neck nucles of patients and controls. International J. Rehabiltation and Health, 2:1-18, 1996.

Edgerton VR, Wolf SL, Levendowski DJ: Theoretical basis for patterning EMG amplitudes to assess muscle dysfunction. Medicine and Science Sports and Exercise, 28:744-751, 1996.

Wolf SL, Segal RL, Catlin PA, Kantos H, Pate P, Raleigh T, Tschorn J: Determining consistency of elbow joint threshold angle in spastic elbow flexor muscles. Phys. Ther., 76:586-600, 1996.

Wolf SL, Segal RL: Downtraining human biceps-brachii spinal stretch reflexes. J. Neurophysiol., 75:1637-1645, 1996.

Wolf SL, Segal RL, Heter ND, Catlin PA: Contralateral and long latency effects of human biceps brachii stretch reflex conditioning. Exp. Brain Res., 107:96-102, 1995.

Wolf SL, Catlin PA, Blanton S, Edelman J, Lehrer N, Schroeder D: Overcoming limitations in elbow movement in the presence of antagonist hyperactivity. Phys. Ther., 74:35-44, 1994.

Wolf SL, Barton LA: Learned nonuse in the hemiplegic upper extremity. In Gordon WA (ed), Advances in Stroke Rehabilitation. Anover Medical Publishers: Boston, 1993, pp. 79-86.

Wolf SL, LeCraw DE, Barton LA, Jann BB: A comparison of motor copy and targeted feedback training techniques for restitution of upper extremity function among neurologic patients. Phys Ther, 69:719-735, 1989.

Wolf SL, LeCraw DE, Barton LA, Jann BB: Forced use of hemiplegic upper extremities to reverse the effect of learned non-use among chronic stroke and head injured patients. Exp Neurol, 104:125-132, 1989.

Evatt ML, Wolf SL, Segal RL: Modification of human spinal stretch reflexes: Preliminary studies. Neurosci Letters, 105:350-335, 1989.

Wolf SL, Binder-Macleod SA: EMG biofeedback applications to the hemiplegic patient: Changes in upper extremity neuromuscular and functional status. Phys Ther, 63:1393-1403, 1404-1413, 1983.

## BIOGRAPHICAL SKETCH

| NAME | POSITION TITLE |
|---|---|
| **Christina M. Kwasnica M.D.** | **Director of Brain Injury Rehabilitation** |

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| University of Arizona Tucson, AZ | BA | 1991 | Political Science |
| Northwestern University Medical School Chicago, IL | MD | 1995 | Medicine |

**POSITIONS:**

Resident Physician Northwestern University Medical School/Rehabilitation Institute of Chicago Department of Physical Medicine and Rehabilitation Chicago, IL 1995-1999

Clinical Instructor and Cognitive Neurology Fellow Northwestern University Alzheimer's Disease Center Departments of Neurology and Physical Medicine and Rehabilitation Chicago, IL 1999-2000

Director of Brain Injury Rehabilitation Barrow Neurological Institute Phoenix AZ 2000-present

**PROFESSIONAL AFFILIATIONS:**

Diplomate, American Board of Physical Medicine and Rehabilitation

Fellow, American Association of Physical Medicine and Rehabilitation

Diplomate, Association of Academic Physiatrists

**AWARDS AND HONORS:**

Seabury Foundation Endowed Research Resident- July 1998-June 1999

NIH National Research Service Award Fellowship- F32 NS10858-01 August 1999-August 2000

Sara Baskin Award for Research Excellence- Rehabilitation Institute of Chicago- May, 1999

President's Citation- 62nd Annual Assembly of the American Academy of Physical Medicine and Rehabilitation- for outstanding paper presentation- "Predictors of Ambulation in Stroke Rehabilitation"

**RESEARCH PROJECTS ONGOING OR COMPLETED DURING THE LAST THREE YEARS:**

*Current*

Predictors of Ambulation in Stroke Rehabilitation with Dr. Richard Harvey, Rehabilitation Institute of Chicago

*Pending*

Unilateral Neglect and the Relationship of Measurements with Function

*Prior*

Bromocriptine in Unilateral Neglect- F32 NS10858-01
NIDRR Stroke Research and Training Center- Rehabilitation Institute of Chicago

**PEER REVIEWED PUBLICATIONS:**

Kwasnica, CM and Heinemann, A. "Coping with Traumatic Brain Injury: Representative Case Studies," Archives of Physical Medicine and Rehabilitation, April 1994, 384-389.

Grujic, Z, Mapstone, M, Gitelman, D, Weintraub, S, Johnson, N, Hays, A, Kwasnica, CM, Harvey, RL, and Mesulam, M. "Dopamine Agonists Reorient Visual Exploration Away from Neglected Hemisphere," Neurology, December 1998.

Kwasnica, CM. "Unilateral Neglect after Right Hemisphere Stroke- a Review of the Syndrome and Management," Critical Reviews in Physical Medicine and Rehabilitation, accepted for publication December, 2000.

SELECTED RECENT ABSTRACTS AND PRESENTATIONS:

Kwasnica, CM, Harvey, RL, and Mullarkey, C. "Predictors of Ambulation in Stroke Rehabilitation," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November, 2000

Kwasnica, CM, Cherney, L, and Harvey, RL. "Unilateral Neglect and Relationships with Functional Outcomes," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November, 1998.

Kwasnica, CM, Grujic, Z, Mapstone, M, and Harvey, RL. "Bromocriptine Effect on Unilateral Visual Neglect After Right Hemisphere Infarct: A Pilot Study," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November, 1997.

Managing Neglect Syndrome after Stroke: A Complete Experience- Annual Assembly of the American Academy of Physical Medicine and Rehabilitation, Novermber, 1998.

Managing Neglect Syndrome after Stroke: A Complete Experience- Annual Multidisciplinary Stroke Course- Rehabilitation Institute of Chicago, April 1999

Pharmacology of Brain Injury- Rehabilitation Institute of Chicago- December 2000

Non-traumatic Brain Injury- Rehabilitation Institute of Chicago- December 2000

Pharmacologic Approaches to Motor Recovery after Stroke- Annual Multidisciplinary Stroke Course- Rehabilitation Institute of Chicago- April 2000

Atypical Dementias- Grand Rounds- Ingalls Hospital- Chicago, IL- April 2000

Neuroplasticity and Rehabilitation- Grand Rounds- Rehabilitation Institute of Chicago- July 2000

EXHIBIT C

## BIOGRAPHICAL SKETCH

| NAME | POSITION TITLE |
|---|---|
| Douglas E. Wendelboe | Software Consultant; President, Penn Microsystems |

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| Pennsylvania State University, State College, PA | BS | 1972 | Electrical Engineering |
| University of Pennsylvania, Philadelphia, PA | MS | 1976 | Electrical Engineering |

RESEARCH AND PROFESSIONAL EXPERIENCE

1998-Present Software Consultant, BTI Consultants, Tempe, AZ. Design of hardware and software for medical devices

1981-Present President, Penn Microsystems. Consulting on microprocessor-based products. Medical device projects include:

- Hand-held Blood Prothrombin-Time Measuring Device, San Jose, CA, 2000-Present
- Designed and implemented the Automated Calibration and Test System for the Bone Growth Stimulator, Phoenix, AZ, 1999-2000
- Firmware enhancements for an electromagnetic Bone Growth Stimulator, Phoenix, AZ, 1997-1999
- Developed an Automated Active Burn-In System for the Bone Growth Stimulator, Phoenix, AZ, 1996-1997
- Designed and implemented firmware for Nerve Integrity Monitor Instrument, Jacksonville, FL, 1994-1995
- Designed, implemented, and maintained the firmware for a line of Micro-titer Plate Readers, Winooski, VT, 1982-1985
- Designed and implemented the complete firmware for a Pacemaker Systems Analyzer, Winooski, VT, 1980-1981

1977-1981 Senior Associate Engineer, IBM Corp., Essex Junction, VT

1976-1977 Senior Product Engineer, Honeywell Corp., Ft. Washington, PA

1972-1976 Design Verification Software Engineer, UNISYS (Sperry-Univac), Blue Bell, PA

PROFESSIONAL PUBLICATIONS

"Recommended Use of the PL/M Computer Language in Safety-Related Systems," Report for the Nuclear Regulatory Commission, NUREG/CR-6463, June 1996

Co-publisher of the Annual "Arizona High Tech Directory"

Columnist for the "Arizona High Tech Times" newspaper

PROFESSIONAL

IEEE Computers, IEEE Software, IEEE Management, IEEE Biomedical

American Society for Quality

TECHNICAL SKILLS

Languages: Keil C51 w/uVision2, IAR C, PIC-C, 8051, 8x86, 68xx, 68xxx assembler, Microchip PIC, Hitachi H8 assembler, TMS320C54x Algebraic assembler, National Instruments LabWindows/CVI, Microsoft Visual C++, Visual Basic

RTOS: uC/OS-II, QNX, Keil RTX-51, familiarity with VxWorks, Tornado

Microprocessors: Intel 8051, 80251, 8X93x USB, Intel 80x86, 80188, 386EX, 68HC05, 68HC08, 68HC11, 68xxx family, Hitachi 6303, H8S/2134, Microchip PIC16C74, 16C65, ST Micro ST10F167/168

In-Circuit Emulation: Intel ICE 8051, 8085, 80188, 80x86, Nohau EMUL51-PC: 80C552, 89C51RD2, Microchip PIC-Master & others

Peripheral Buses: I²C, CAN v2.0, USB, Motorola SPI, Dallas Semiconductor interfaces

Design Standards: IS)-9001 Design Quality Standards, FDA (97-4179) Medical Device Quality Systems Standards, FDA 510(k), FDA Pre-Market Approval (PMA)

Bus Boards: PC/104 Bus, STD Bus, VME Bus

Logic: SPICE Simulation, Programmable Logic Compilers

Network: TCP/IP, WATTCP

Database: MS SQL7, Oracle, Informix

## BIOGRAPHICAL SKETCH

| NAME | POSITION TITLE |
|---|---|
| Edward J. Koeneman | Consultant |

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| Arizona State University, Tempe, AZ | BSEET | 1992 | Electronic Engineering |
| Arizona State University, Tempe, AZ | MT | 1994 | Electronic Engineering |

POSITIONS

| | |
|---|---|
| 1999-Present | BTI Consultants, Consultant. |
| 1997-1999 | Adtron Corp., Mesa, Arizona. Product Manager, Data Storage Devices. |
| 1997 | PCI Medical, Phoenix, Arizona. Design Engineer, Medical Electronics. |
| 1995-1997 | Prescom Electronics, Mesa, Arizona. Chief Engineer, Contract Electronic Design and Manufacturing. |
| 1988-1995 | Harrington Arthritis Research Center, Phoenix, Arizona. Lab Coordinator for Orthopaedic Resident Projects, Mechanical Testing. |

PEER REVIEWED PUBLICATIONS

Koeneman, E.J., J.A. Lerman, R.J. Haynes, J.B. Koeneman, W. B. Wong, "A Biomechanical Comparison of Gardner-Wells Tongs and Halo Device Used for Cervical Spine Traction," SPINE, Volume 19, Number 21, pp. 2403-2406, 1994.

Koeneman, E.J., N.R. Crawford, A.G.U. Brantley, C.A. Dickman, "An Apparatus Applying Pure Nonconstraining Moments To Spine Segments In Vitro," SPINE, Volume 20, Number 19, pp. 2097-2100, 1995.

SELECTED PRESENTATIONS

Koeneman, E.J., J.A. Lerman, J.E. Maisel, J.B. Koeneman, "Electromyographic Analysis of the Hockey Slapshot," Presented at 1994 Fall Meeting of the Biomedical Engineering Society.

AWARDS AND HONORS

IEEE Outstanding Student Achievement Award, 1993

## BIOGRAPHICAL SKETCH

| NAME | POSITION TITLE |
|---|---|
| Donald E. Herring | Senior Industrial Design Consultant |

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| INSTITUTION AND LOCATION | DEGREE | YEAR CONFERRED | FIELD OF STUDY |
|---|---|---|---|
| American University, Washington, DC | BA | 1967 | Govt. and Public Admin. |
| Arizona State University, Tempe, AZ | BS | 1982 | Product Design |
| Arizona State University, Tempe, AZ | MSD | 1993 | Human Factors and Design |

PROFESSIONAL EXPERIENCE

| | |
|---|---|
| 2001-Present | Senior Industrial Design Consultant, BTI Consultants, Tempe, Arizona |
| 1998-Present | Assistant Professor, Arizona State University, Tempe, Arizona |
| 1997-1999 | Proprietor, Redfish Design, Phoenix, Arizona |
| 1994-1997 | Assistant Professor, Purdue University, West Lafayette, Indiana |
| 1992-1994 | Exhibit and Industrial Designer, Sunbelt Scenic Studios, Inc., Tempe, Arizona |
| 1991-1992 | Exhibit Designer, Giltspur Exhibits, Phoenix, Arizona |
| 1982-1989 | Senior Project Designer, Mattel Toys, Hawthorne, California |
| 1975 | Arizona Real Estate Sales and Brokerage, Phoenix, Arizona |
| 1973 | Specialist, United States Treasury Department, Washington, D.C. |
| 1972 | Foreman, Athens Paint & Drywall Company, Alexandria, Virginia |
| 1968 | OJT Contract Writer, Washington Urban League, Washington, D.C. |
| 1968 | Capitol Policeman, United States Capitol Building, Washington, D.C. |

PRINCIPAL PROFESSIONAL PUBLICATIONS AND PRESENTATIONS

"Children's Computer Human Factors and Seating Recommendations" (For Our Greatest Future Resource), Natural Resources, 1995 IDSA Design Education Conference Proceedings, Santa Fe, New Mexico, September 1995

"Twenty Years Later: What Are the 1982 Graduates of an Industrial Design Program Doing in the New Millennium?," Gumbo, 2000 IDSA Design Education Conference Proceedings, New Orleans, Louisiana, September 2000

MEMBERSHIPS IN SCIENTIFIC AND PROFESSIONAL SOCIETIES

Human Factors and Ergonomics Society of America
Arizona Chapter Member of the Human Factors and Ergonomics Society of America
Industrial Design Society of America (IDSA)
The Arizona IDSA Chapter Secretary (Founding member and officer)
The Indiana IDSA Chapter Secretary/Treasurer (Resigned, April, 1997)

PATENTS

U.S. Patent 4,787,876 - Toy Musical Play Set, 11/29/88, assigned
U.S. Patent 4,673,373 - Transformable Toy Block, 6/16/87, assigned
U.S. Patent 4,645,471 - Busy Ball Child's Toy, 3/7/85, assigned

AWARDS, SCHOLARSHIPS AND HONOR SOCIETIES

Netherlands Toy of the Year Award to Disney Pots and Pans Band based on Originality, Safety and Suitability, 1988

Second Place Award ($2,000.00) in Mattel's Toy of the Year Contest for the Invention and Development of the Double Dooz Transformers Toy Line, 1986

Nominated for the Mattel Toys Presidents Award for Leading a "Brainstorming Event" with 40 Participants Producing 100 Product Concepts for Presentation in Ten Days, 1985

Mattel $2000.00 Discretionary Award for "The First Innovative Preschool Product Line to Come out of Mattel in Eight Years," 1985

Arizona State University Outstanding Senior Industrial Design, 1982

Honorable Mention ($250.00) in Mattel Toy Design Contest, 1982

Awarded Internship at Mattel Toys, 1982

Phi Kappa Phi National Honor Society, 1982

EXHIBIT C

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME | POSITION TITLE |
|---|---|
| Cristobal Neal Eblen, Ph.D. | Director of Planning, Research and Program Evaluation |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Marist College | BA | 1976 | Psychology |
| Marist College | MA | 1978 | Community Psychology |
| Arizona State University | Ph.D. | 1987 | Social Psychology |

NOTE: The Biographical Sketch may not exceed four pages. Items A and B may not exceed two of the four-page limit.

A. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

Post-doctoral Research Fellow (Harrington Arthritis Research Center) 1987-89
Psychologist I (AZ Department of Corrections) 1989-90
Psychologist II (Arizona State Hospital) 1990-91
Research and Statistical Analyst III (AZ Division of Behavioral Health Services) 1991-93
Psychologist II (Southern Arizona Mental Health Center) 1993-96
Psychologist II (AZ Department of Corrections) 1996-97
Research Associate (Community Partnership of Southern Arizona) 1997-2000

B. **Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.

Eblen, C. & Koeneman, J. (1993). A longitudinal evaluation of a four-wheeled walker: Effects of experience. Topics in Geriatric Rehabilitation, 8, 65-72.

Eblen, C. (1992). Evaluation of assistive devices. Topics in Geriatric Rehabilitation, 8, 6-11.

Eblen, C. & Koeneman, J. (1991). A multi-dimensional evaluation of a four-wheeled walker. Assistive Technology, 3, 32-37.

C. **Research Support.** List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of principal investigator identified above.

N/A

## RESOURCES

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory:

KMI leases 1,433 square feet of office and laboratory space. Our lab contains the latest in hardware support tools such as: Logic analyzers, analog & digital oscilloscopes; I2C, USB and CAN bus analyzers; Internet server with TCP/IP tools. We also maintain the latest in software compilers, assemblers, simulators, and other software development tools for microprocessors and systems.

We have a complete model shop for the development of prototypes. This includes saws, sanders drill press and a complete supply of hand tools. We have a complete drafting facility.

These facilities are dedicated to the development of the device described in this proposal and to extensions of the design.

Clinical:

All clinical evaluations will be done at the Barrow Neurological Institute (BNI) of St. Joseph's Hospital in central Phoenix. It was first accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF) in 1988. BNI has a state-of-the-art rehabilitation facility and participates in many clinical rehabilitation research studies. Space and equipment for the clinical evaluations will be available for this study.

Animal:

NA

Computer:

Various computer simulation programs such as AutoCAD, Photoshop, Ilustrator, Humanoid, Perception Video Capture Hunamoid run on eight Pentium computers.

Office:

The office has complete facsimile, copying and printing facilities.

Other:

The KMI facility is adjacent to BTI Consultants that provides secretarial and technician support and miscellaneous consulting on an as needed basis.

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

See above.

# INTRODUCTION

*The comments that follow are in sequential response to the concerns expressed by the reviewers on the summary statement of the previous grant proposal. Their concerns are summarized, followed by our response. Where appropriate and relevant, the responses are numbered or lettered and the narrative page number where the total response can be found is given next. Additions in this proposal are in italics.*

***Points of Resume and Summary:***

*1(Pages 22 - 25,)* ***Insufficient details about clinical trial protocol.*** *At the suggestion of the first reviewer we have changed the protocol to involve only able-bodied participants (caregivers and clinicians).*

*2. (Pages 22 - 24 )* ***Need to better focus on design development and demonstration of usability and feasibility.*** *The study using caregivers and clinicians will measure and record usability, durability, effectiveness of the feedback means, acceptance of the treatment protocols, and safety.*

*3. (Pages 19, 22, 23)* ***Reliability of the EMG signals.*** *The variability of the EMG signals within a treatment and between treatments will be measured on able-bodied subjects.*

*4. (Pages 22 - 24)* ***Rationale for Training.*** *The questionnaires and focus group response from caregivers and clinicians will help evaluate and refine the treatment protocols.*

*5. (Pages 22, 24, 25 )* ***Patient Safety.*** *A Data Safety Management Board (DSMB) was established to review protocols, progress reports, and any incidents.*

*6. (Page 24)* ***Six hours a day may be too long for stroke patients.*** *Again the response of the trial participants will evaluate this question. If this treatment time is too long, shorter treatment intervals over extended periods of time are also feasible with a take home device.*

*7. (Page 22)* ***Healthy subjects should be used.*** *We redesigned the study to follow this suggestion.*

*8 (Page 22)* ***Determine adverse events.*** *A DSMB was included in the study to monitor the pilot study.*

*Reviewer 1:*

*A. (Page 22 )* ***Suggested using normal subjects.*** *We have changed the pilot study accordingly..*

*B.(Pages 19, 22, 24, 25 )* ***Safety.*** *We have added more descriptive information on safety features designed into the device, have added a DSMB, and limited the study to normal participants.*

*C.(Page 19)* ***Force Measurement.*** *We have described our method of calibration of the force sensors and how torque about the wrist is determined*

*D.(Pages 19)* ***Thumb considerations.*** *How the thumb is abducted and how it can be adjusted for each patient is described. Clinician reaction to this method of handling the thumb and the increased tone with wrist extension is sought in the study.*

***E. Use of block.*** *Since we are not using stroke patients, this task practice has been deleted.*

***F. Wolf Motor Function Test*** *Deleted. since stroke patients are no longer included.*

*G.(Pages 22, 24, 25 )****Safety and Adverse Events.*** *See 5. and 8. above.*

***Reviewer 2:***

*The comments by reviewer 2 are all good, valid and need to be addressed when the study is applied to patients. Other comments mirrored comments by reviewer 1 that are addressed above.*

*Reviewer 3: Comments in addition to those of others.*

***H. Number of devices needed.*** *Six devices are needed. However to have devices under modification while some tests are ongoing, 12 devices will be made. The costs are included in the budget.*

*I.(Pages 22, 24 )* ***Detailed Engineering Characterization of the device.*** *A task is included to document the detailed engineering characteristics of the device*

*J.(Pages 6-8)* ***Need person experienced with EMG.*** *Dr. Wolf has written over 30 articles involving EMG and has written a book on the subject. In addition he is a past board member of the Electrokineseology Society and is an assoc. editor of JEM.*

*Reviewer 4: Comments in addition to those of others.*

***K.****(Page 23)* ***Lack of human interface and concern about compliance.*** *We will be evaluating these concerns.*

***L. Medical insurance coverage? This Important question is not germane now but will be a target goal evolving from the Phase II study.***

## RESEARCH PLAN

### A. SPECIFIC AIMS

The **primary purpose** of this project is to improve the restoration of upper extremity physical function of stroke patients by incorporating into one device, the treatment modalities of repetitive practice, and force and electromyographic (EMG) biofeedback. Each of these components may in and of itself demonstrate varying degrees of success in treating stroke patients. The device will assist therapy by supplying increased amounts of information to the physician and therapist while reducing the amount of patient contact time. The device will be adaptable to accommodate the changing paradigm of cerebrovascular accident (CVA) rehabilitation service delivery and to assist in studies designed to refine therapy protocols. The **hypothesis** to be tested is whether it is feasible for this device to *provide a comfortable and safe method of therapy. The first step of sequential hypothesis testing is to demonstrate usability on a wrist and finger joint model. This first step will be deemed feasible and worthy of further exploration if detailed design verification measurements and the responses of normal test subjects indicate the device will be safe and acceptable by patients.*

**The specific aims of this proposal are:**

1. *Document the device design specifications and the patient safety and hazard analysis.*

2. *Document the response of non-affected people to use of the device.*
3. *Refine display methods, software protocols, and patient-device interactions.*

### B. BACKGROUND AND SIGNIFICANCE

Many people have movement disabilities caused by disease or injury. Among the causes are cerebrovascular accident or stroke (CVA), traumatic brain injury, multiple sclerosis, spinal cord injury and Parkinson's disease. This project focuses on stroke; however the results will have application to other causes of movement disability. Stroke is the leading cause of disability in the United States with at least 700,000 new cases each year [1-3]. Over half of these people have residual physical disability. Current stroke therapy is labor-intensive and costly. Often insurance does not cover the cost of full therapy. One estimate is that the United States spends $30 billion per year to take care of stroke survivors. Seventeen billion dollars of this cost is direct medical expenditures and thirteen billion dollars represent an indirect cost due to lost productivity [3]. Another estimate is that the total direct and indirect costs of stroke are $43.3 billion per year [3]. The number of strokes is projected to increase because of the increase in the over 50 "baby boom" population. Also, new pharmaceutical treatments for stroke are projected to increase the number of patients surviving a stroke and increase the percentage of stroke survivors requiring rehabilitation. Therefore, it is not surprising that a recent estimate indicates the prevalence of stroke will more than double over the next 50 years [2].

Because of health care reimbursement reductions, therapy time for stroke patients has been significantly decreased. Currently, a majority of time spent in therapy post-stroke concentrates on helping a patient adapt to their disability by teaching toileting skills and transfers. A consequence of this treatment is the emergence of, "learned nonuse" that hinders the restoration of available function [2]. Most current rehabilitation therapies are administered on a spaced basis. Recently, concentrated therapies have been developed that improve function in

CVA patients by reversing the effects of "learned nonuse"[4]. Animal studies suggest that learned nonuse is established immediately after the initial organic damage. A patient is punished for trying to use the affected limb and is rewarded for using other parts of the body. Over time, healing of the organic damage occurs but the suppression of use learned in the acute phase remains in force [4]. As discussed by Taub [4], many of the therapies that have been shown to be effective in restoring function involve massed practice. Physical Therapy training techniques were used by Bach-y-Rita [5,6] and Franz, Scheetz, and Wilson [7]. Significant improvement in limb function was obtained in chronic CVA patients. Training techniques based on EMG biofeedback improved motor ability of chronic CVA patients, as demonstrated in studies by Wolf [8,9], Basmajian [10, 11], and Balliet [12]. Repetitive concentrated practice produced large therapeutic effects for lower limb function [13, 14, 15]. Taub (2,32) has systematically studied a variation of forced use of hemiplegic extremities, originally described by Wolf (31,35,36). Taub has labeled this therapy Constraint-Induced (CI) Movement Therapy [2, 32]. His group has shown positive results in controlled randomized studies [16]. Some of these experiments compared several massed therapy techniques and all showed very large increases in limb use over the treatment period.

Two very sophisticated robot systems are being developed for treatment and evaluation of CVA patients [1, 17]. These devices have shown some effectiveness in treatment of CVA patients and have developed very useful data for understanding recovery mechanisms, however, the current cost of these systems precludes their widespread clinical use [18].

Other studies show that measured EMG can be used to trigger neuromuscular electrical stimulation in restoring function to CVA patients [26, 27, 28, 29]. However, the discomfort of surface neuromuscular stimulation significantly limits the clinical implementation of this modality for persons with hemiplegia [34]. EMG biofeedback treatment of stroke patients has also shown some success [30, 31, 12, 8]. This treatment uses surface electrodes to capture the electrical activity of a selected muscle group. An electronic unit converts the signals into visual or audio information for the patient. This information is used by the patient to augment or decrease muscle activity.

A device that has a venerable history in supplying motion to assistive devices is the pneumatic artificial muscle. The artificial muscle exhibits many of the properties of human muscle. The device consists of an expandable internal bladder, e.g., a rubber tube, surrounded by a braided shell. When the internal bladder is pressurized, it expands radially against the braided shell. The pressure on the inside of the braid causes it to contract. Braided finger traps used to hold fingers on traction devices contract radially when pulled. The **air muscle** works in the same manner only in the opposite direction, i.e., increasing the diameter causes it to shorten. Like human muscle, the device has spring-like characteristics, is flexible, and is lightweight. The force-deflection characteristics can be made similar to those of human muscle. This type of device was first used in the 1950's for powered braces [19, 20]. Pressurized air canisters or accumulators that are recharged by air compressors supply air. Major advantages of the air muscle are its flexibility and ease of adaptation to address the specific loss of function exhibited by a patient. This type of device is often referred to as the McKibben Artificial Muscle The device has three times the pull force of an air piston of the same cross sectional area **The potential utility of this device resides in its unique combination of attributes: low cost, light-weight, low profile, and low noise operation**. The device has not been used extensively, because it has been applied in the wrong applications and has suffered from the lack of engineering in critical areas. Research on the application of the air muscle has been revived by the University of Washington [21, 22, 23, 24, 25]. The Shadow Organization in England uses the air muscle to operate biped and multiped robots [33].

## C. PRELIMINARY STUDIES

The labor-intensive and long treatment times of forced practice make effective rehabilitation expensive. A promising approach to providing a lightweight, low-cost stroke therapy device is a system that synergistically

combines three modes of feedback that individually have been shown to be effective (visual presentation of desired motion, resistive-force of wrist flexor muscles and EMG activity of the extensor muscles). We have constructed a prototype of an air muscle powered therapy device for the fingers and wrist that has the adaptability to be used in current treatment modalities and also in the refinement of rehabilitation methods. Figure 1 is a drawing of the device. An air muscle is attached to the proximal forearm. Activation of the air muscle rotates a bar that extends the wrist and fingers and operates *a modified Watt six-bar* mechanism that extends the fingers. Wrist extension position is measured by a potentiometer that is incorporated in the device pivot. Resistance to extension is measured by force sensitive resistors (FSRs). Thus the FSR output is a measure of the resistance of finger and wrist flexor muscles. *The FSRs are calibrated after each device is assembled. A load cell is inserted between the activation bar on the mechanism and muscle. The mechanism is fixed in six different degrees of flexion-extension. The output of the FSRs is compared to the load cell output. The torque about the wrist at each wrist position is calculated by multiplying the muscle force by the distance to the line of action of the air muscle. Closely spaced surface electrodes measure wrist extensor EMG activity. The location of the EMG electrodes is determined for each patient by the therapist. The skin is rubbed 20 times with alcohol soaked gauze pads. The EMG output is used to measure the relative recruitment of selected extensor muscles and used to feedback the information to the patient to reinforce correct recruitment. Session to session variation in EMG values are recorded but we do not believe they will be a primary indicator of patient progress.*

*Wrist and Finger Motion*

*The air muscle drives the fingers and wrist into extension by moving a mechanical linkage. The linkage is designed to move the fingers and wrist in a spiral fashion. Excessive force on the hand is prevented in several ways. A micro-compressor was chosen that has a maximum output pressure of 28 psi. This limits the maximum force supplied by the air muscle. The air muscle is a very compliant drive with the maximum force output at the fully flexed position where the stretch reflex resistance of the flexor muscles is minimum. As extension proceeds, the stretch reflex increases resistance to motion. If a large resistance is encountered during extension, the air muscle stretches and limits the range of motion. Since spastic flexor muscles are velocity sensitive, the velocity of actuation was chosen to be 5 degrees per second with no loading. With the weight of a flaccid hand this rate decreases to 3.8 degrees per second and with mild resistance the rate is 2.7 degrees per second. Experiments by Richard Herman showed only small increases in muscle tone occurred for very spastic hemiplegics due to velocity at rates below 6 degrees per second [40]. The rate in the KMI device is physically controlled by the volume capacity of the micro-compressor and the resistance in the pneumatic circuits. To prevent excessive extension of the wrist, a physical stop is also provided that limits motion of the activation bar at 60 degrees of wrist extension. A safety panic switch that releases the air pressure is also provided on a tether and is placed close to the subject's non-treating hand. An orthoplast® thumb splint is provided with the device. The fitting clinician can adjust the amount of abduction appropriate for a particular patient.*

A microprocessor controls the activation of the air muscle by operating the microcompressor and air valves. Wrist position is displayed as a bar graph on the LCD. The changing goal for active wrist motion is displayed as a line on the graph. One line of multi-color light emitting diodes (LEDs) indicates the degree of flexor resistance torque as measured by the force sensitive resistors. A second line of LEDs indicates the EMG activity of the wrist or finger extensors. The microcompressor, air valves, microprocessor, and the LCD are in a plastic box that sits on a table during therapy sessions. A coiled cable assembly that contains the electrical wires and air hose connects the box to the activation device. This system is a self-contained, mobile device that provides visual feedback of wrist and finger position, EMG extensor activity and wrist flexor resistive torque. The firmware in the microprocessor has been designed to be well-structured using object-oriented programming techniques. Use of these techniques yields more reliable code having fewer discrepancies and problems. Each of the object components was tested separately (component testing). When the firmware was integrated with

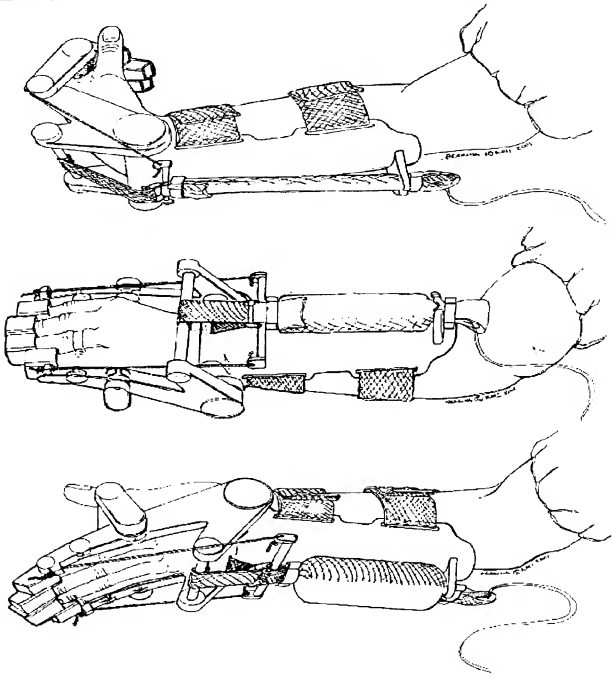
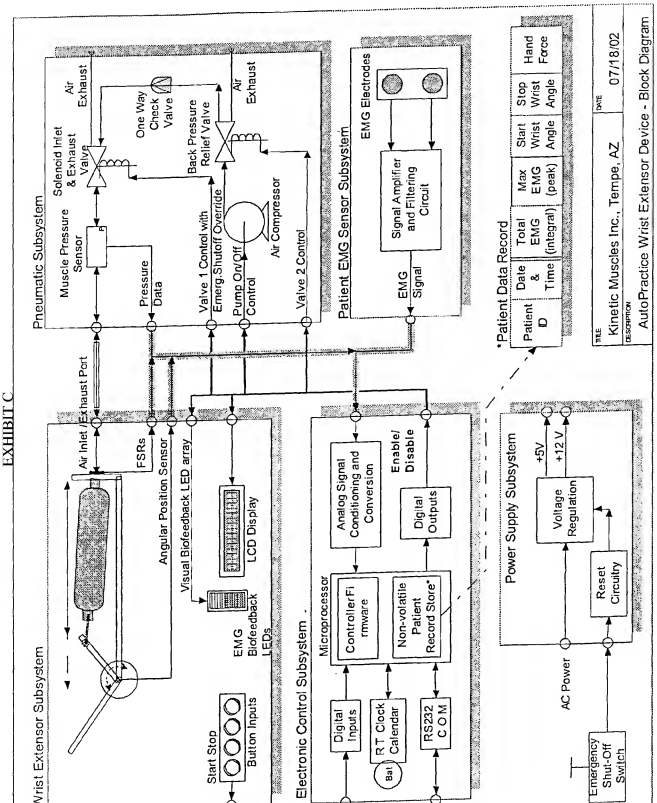


**Figure 1** Therapy Device in Flexion, Neutral and Extension;
Shrouding, LEDs and Control Box not shown for Clarity

EXHIBIT C


Wrist Extensor Subsystem
Air Inlet/Exhaust Port
FSRs
Angular Position Sensor
Visual Biofeedback LED array
LCD Display
EMG Biofeedback LEDs
Start Stop Button Inputs
Electronic Control Subsystem
Microprocessor
Digital Inputs
RT Clock Calendar
Batt
RS232 COM
Controller Firmware
Non-volatile Patient Record Store
Analog Signal Conditioning and Conversion
Digital Outputs
Enable/ Disable
Power Supply Subsystem
AC Power
Emergency Shut-Off Switch
Reset Circuitry
Voltage Regulation
+5V
+12V
Pneumatic Subsystem
Muscle Pressure Sensor
Pressure Data
Solenoid Inlet & Exhaust Valve
Air Exhaust
One Way Check Valve
Back Pressure Relief Valve
Air Exhaust
Valve 1 Control with Emerg.Shutoff Override
Pump On/Off Control
Air Compressor
Valve 2 Control
Patient EMG Sensor Subsystem
EMG Electrodes
Signal Amplifier and Filtering Circuit
EMG Signal
*Patient Data Record
Patient ID
Date & Time
Total EMG (integral)
Max EMG (peak)
Start Wrist Angle
Stop Wrist Angle
Hand Force
TITLE
Kinetic Muscles Inc., Tempe, AZ
DATE
07/18/02
DESCRIPTION
AutoPractice Wrist Extensor Device - Block Diagram

the electronic hardware, the complete system was tested (system integration testing). Finally, the operation of the complete device was validated and verified for function by comparing to the design requirements established at the project beginning. The essence of the design requirements is described in this proposal. A block diagram of the system is shown in Figure 2. The real-time clock/calendar is powered by a battery mounted on the printed circuit board when the power is off. The clock maintains the time and date continuously. Records of patient use, active range of motion, extensor resistive torque, and EMG activity are recorded with a time stamp in a non-volatile serial EEPROM memory device. Data is kept safe, even when no power is applied to the memory. These records can be downloaded to a Windows application on the therapist's personal computer. The results are sorted by participant and tabular and graphical displays made available for viewing.

## H. EXPERIMENTAL DESIGN AND METHODS

*Device Characterization*

*The purpose of this experiment is to characterize the pneumatic muscle. The characterization will be done by inflating a muscle thus contracting it, adding a sequence of loads and measuring the displacements of the muscle. This is repeated for different pressures of inflation. The experiment will include the testing of the passive force-length properties of the muscles, plugged and unplugged muscles and the reproducibility of muscles of the same type and length. In addition, full engineering characterization of the fully assembled device will be done.*

*Pilot Study*

*A pilot study of able-bodied participants will be conducted to determine the usability, safety and feasibility of using this device on stroke patients.*

*Data Safety Monitoring Board (DSMB) – This board will be established to review the progress of the study with a special interest in participant safety. Dr. Kwasnica, Dr. Wolf, Kay Wing, and Deborah Taylor will be on the board. They will review participant protocols, progress reports and any incident reports.*

*Participant Population – Five clinicians who treat stroke patients and five caregivers of stroke patients will be recruited. The clinicians will have a minimum of three years experience in treating stroke patients.*

*Evaluation –Deborah Taylor and Kay Wing, both licensed physical therapists will administer the program. The therapist will explain the operation and purpose of the device. A brochure describing the device and contact information will be provided the participant. The therapist will then place the EMG electrodes on the patient and attach them to the device. The therapist will demonstrate several treatments of the device. The device will be removed and the patient asked to attach the device and start treating without any help. The participants will be required to return after one week and at the end of two weeks for completion of questionnaires regarding acceptability of the device and evaluation of features. The participants will be asked their impression of the device weight and bulkiness, their fatigue during therapy, the effectiveness of the LED and LCD feedback methods, the reliability of the device and they will be asked to provide suggestions. Ratings will be on an ordinal scale.*

*Protocol – The participant is instructed to try to extend the wrist when a beep is heard. The EMG activity of the wrist extensors and the motion of the wrist are recorded in the memory of the device and displayed for the participant. The participant will be instructed to use the device for at least 6 hours a day, although more treatment is allowed. The treatments do not have to be continuous. The participanat can start and stop the device at any time. The first 2 hours will emphasize EMG and joint position feedback. During the second 2 hours the flexor resistance torque from the flexors will be used as the feedback signal to help the patient reduce any flexor spasticity. The final 2 hours of therapy will have both extensor EMG and flexor resistance torque as*

*achieved at the beginning of a day and at the end of each day is recorded in memory. This information will provide us with accurate information about participant compliance. The memory of the device will be downloaded onto a PC in the clinic. A summary chart graphically displaying the number of hours of use a day by the participant, the range of motion and the active range of motion by day will be displayed and the charts printed for the participant file.*

Data Analysis - Measures: There are three types of data collected in this study:

*(1) The number of hours of use per day by the participant. This is a measure of compliance with treatment.*

(2) *Recording, Displaying and Reporting of Functional Measures such as range of motion, EMG Biofeedback and flexor resistive muscle tone.*

(3) *Participant acceptance of the device as recorded in questionnaires and a final Focus Group.*

Evaluation

*Participant acceptance of the device and suggested improvements will be entered into the design control system for the device for evaluation. Correlations will be calculated between reported compliance and actual hours of use.*

*The device will be considered acceptable and feasible if participant compliance is sufficient and the response to the questionnaires indicates that the device is useable and considered safe.*

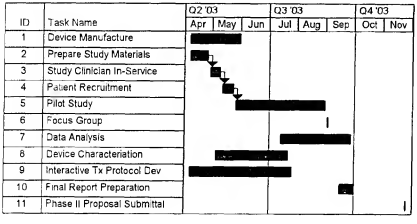
Limitations - *While the numbers of minority and ethnic people in this study preclude statistically significant comparisons, the main purposes of this study are to refine the protocol and the device for a Phase II study and to investigate feasibility, acceptance and safety of this therapeutic device.*

Design Issues – The sensitivity of the EMG measurement to forearm motion and relative motion of muscles with respect to skin will be examined. The repeatability of placement of the electrodes from use to use will also be evaluated. Skin sensitivity to the pressure of the device or type of material will be examined.

Project Plan – *Three tasks will begin at the beginning of the project. Manufacture of the study devices will begin, the documentation to be provided to study participants will begin preparation, and development of innovative interactive treatment firmware will begin. Participant information kits will be sent to them describing the purpose and protocol of the study. Follow-up phone calls will be made to answer any questions and ascertain their willingness to participate in the study. Just before beginning the study, an extensive in-service session will be conducted for the therapists that will be conducting the patient training. Task 5 is the therapy portion of the study. Two clinician and two caregiver participants will begin treatment at the start of Task 5. After one week they will return for completion of questionnaires and debriefing. Then one week is scheduled for adjustment of the devices and firmware based on participant input. Then the three remaining clinicians and three caregivers will be given devices for one week of treatment. After their return and completion of questionnaires three weeks is scheduled for making adjustments in the devices and firmware. Then the two groups of two will return for another week of treatment. This week is followed by one week for*

*adjustments and then the final group comes in for the beginning of one week of treatment. At the end of the study, a Focus Group will be held to have interaction between the participant therapists and caregivers in evaluating the device and providing further suggestions. A report of the Focus Group will document the participant's opinions of usability and safety of the device. Concurrent with the participant evaluations, performance characterization of the device, update of the hazard analysis and adjustments to the firmware and displays will be made. A final report addressing the feasibility of the device, device changes suggested by the results, and protocol changes suggested for the Phase II study will be prepared. Assuming feasibility is demonstrated, an application for Phase II funding will be prepared for December 1, 2003, submission.*

Table I Gantt Chart




*The* **deliverables** *of this Phase I study are: (1) a complete characterization of the device performance and hazard analysis, (2) refined displays, donning and doffing procedures and other device features that make the device user friendly, (3) the documented opinions of caregivers and clinicians as to usability, acceptance, and safety of the device.*

*The feasibility of using this device in a Phase II study involving stroke patients will be determined by the safety and usability conclusions.*

## *E. HUMAN SUBJECTS*

Involvement of Human Subjects: The purpose of the device under evaluation in this proposal is to facilitate the application of concentrated practice for stroke patients. Numerous studies, most notably by Taub and Wolf, have provided this therapy through one-on-one contact with physical therapists. In all of these studies there is no reason to believe that this intervention provides selective benefits (or limitations) based upon gender or racial attributes. In this study the gender and minority status will be recorded and reported for all participants. The numbers are so small that little meaningful statistical conclusions can be made although physiological and functional performance will be reported for these categories. Children less than 18 years of age are excluded because an immature nervous system may respond differently to this therapy than a mature one and the low number of young patients available for this short study.

Human Research Material: *Participants will be in two groups. Group I will be clinicians that have treated stroke patients for a minimum of three years. The identity of participants will be protected. Participants in this trial will receive codes to protect their identity throughout the study.*

Recruitment of subjects: *The clinician participants will be recruited by the two physical therapists that are familiar with this device (Kay Wing and Deborah Taylor). The caregivers of stroke patients will be recruited by Dr. Kwasnica, Kay Wing, and Deborah Taylor.*

Potential Risks: The physical risk involved with using this device is overextending a joint and causing soft tissue damage. *To control this risk the range of motion of the mechanism is limited to the physiological range of motion of a normal person. To protect against overload of spastic muscles or contractures, the amount of force the device can provide is limited. A panic button is provided that removes load and shuts the device down.* Another risk is fatiguing the patient and causing anxiety. The risks involved with use of EMG electrodes are skin irritation. A control on this risk is that the participant has the right to drop out of the study at any time.

Minimization of Risk: The risk of overstretching a joint is controlled in several ways. There is a physical stop incorporated in the device that prevents wrist extension over 60°degrees of extension. If the wrist is stopped by an obstruction, the force is limited by the low stiffness of the air muscle actuator. Also, if the torque measured by the extension bar exceeds 8 newton meters (the resistive torque of the finger and wrist flexors), the air is exhausted and the device shut down. A panic button is also provided for easy access by the unaffected hand that will also exhaust the air muscle and shut the device down if the patient is feeling any discomfort, fatigue or anxiety.

Reasonableness of Risk: As noted above, effective means of controlling the risks are designed into the device. When one realizes that the eventual potential benefit to stroke patients can be substantially enhanced function in real world activities and improved quality of life beyond that achieved during the early rehabilitation interval, the risks are not significant.

FDA Approval: It is our opinion that this device is not a significant risk device and that only IRB approval is required. We will submit the protocol, a description of the device, a patient consent form, and an evaluation of the hazards involved in use of the device and how we are controlling these hazards to the IRB.

## F. VERTEBRATE ANIMALS

Not applicable.

## G. LITERATURE CITED

1. H.I. Krebs, B.T. Volpe, M.L. Aisen, N. Hogan, "Increasing Productivity and Quality of Care: Robot-aided Neuro-rehabilitation", Journal of Rehabilitation Research and Development, Vol. 37, No. 6, Nov/Dec, 2000, PP 630-652.

2. E. Taub, G. Uswatte, R. Pidikiti, "Constraint-Induced Movement Therapy: A New Family of Techniques with Broad Application to Physical Rehabilitation – A Clinical Review", Journal of Rehabilitation Research an Development, Vol. 36, No. 3, July 1999, pp 237-251.
3. G.E. Gresham, "Post-stroke Rehabilitation", U.S. Dept of Health and Human Services, Public Heath Service, Agency for Health Care Policy and Research, May 1995, AHCPR publication # 95-0662.
4. E. Taub, "Guest Editorial: New Discovery Equals Change in Clinical Practice", Journal of Rehabilitation Research & Development, Vol. 36, No. 3, July 1999, pp. vii-viii.
5. P. Bach-y-Rita, E. Wicab Bach-y-Rita, "Biological and Psychosocial Factors in Recovery from Brain Damage in Humans", Canadian Journal of Psychology, 1990, Vol. 44 pp. 148-65.
6. P. Bach-y-Rita, "Recovery from Brain Injury", Journal of Neurological Rehabilitation, 1993, Vol. 6, pp. 191-9.
7. S.I. Franz, M.E. Scheetz, A.A. Wilson, "The Possibility of Recovery of Motor Functioning in Long-standing Hemiplegia", Journal of the American Medical Association, 1915, Vol. 65, pp. 2150-4.
8. S.L. Wolf, S.A. Binder-Macleod, "Electromyographic Biofeedback Applications to the Hemiplegic Patient: Changes in Upper Extremity Neuromuscular and Functional Status", Physical Therapy, 1983, Vol. 63, pp. 1393-403.
9. S.L. Wolf, "Electromyographic Biofeedback Applications to Stroke Patients: A Critical Review", Physical therapy, 1983, Vol. 63, pp. 1448-55.
10. J.V. Basmajian, E.M. Regenos, M.P. Baker, "Rehabilitation Stroke Patients with Biofeedback," Geriatrics, 1972, Vol. 32, pp. 85-8.
11. B.V. Basmajian, C.G. Kukulka, M.G. Narayan, K. Takebe. "Biofeedback Treatment of Foot-drop After Stroke Compared with Standard Rehabilitation Technique: Effects on Voluntary Control and Strength", Archives of Physical Medical Rehabilitation, 1975, Vol 561, pp 231-6.
12. R. Balliet, B. Levy, K.M.T. Blood, "Upper Extremity Sensory Feedback Therapy in Chronic Cerebrovascular Inpatients with Impaired Expressive Aphasia and Auditory Comprehension," Archives of Physical Medical Rehabilitation, 1986, Vol. 61, pp 301-10.
13. C. Butefisch, H. Hummelsheim, P. Kenzler, K-H Mauritz. "Repetitive Training of Isolated Movements Improves the Outcome of Motor Rehabilitation of the Centrally paretic Hand," Journal Neurological Science, 1995, Vol. 130, pp. 59-68.
14. S. Hesse, C. Bertelt, A. Schaffrin, M.S. Malezic, K-H. Mauritz, "Restoration of Gait in Nonambulatory Hemiparetic Patients by Treadmill Training with Partial Body-weight Support", Archives of Physical Medicine and Rehabilitation, 1994, Vol 75, pp. 1087-93.
15. S. Hesse, C. Bertelt, M.T. Jahnke, "Treadmill Training with Partial Body Weight Support Compared with Physiotherapy in Nonambulatory Hemiparetic Patients", Stroke, 1995, Vol. 26, pp. 976-81.
16. E. Taub, J.E. Crago, G. Uswatte, "Constraint-Induced Movement Therapy: A New Approach to Treatment in Physical Rehabilitation", rehabilitative Psychology, 1998, Vol43, pp. 152-70.
17. D. Reinkensmeyer, L.E. Kahn, M. Averbunch, A. McKenna-Cole, B.D. Schmit, W. Zev Rymer, "Understanding and Treating Arm Movement Impairment after Chronic Brain Injury. Progress with the ARM Guide," Journal of Rehabilitation Research and Development Vol. 27, No. 6, Nov/Dec 2000, pp. 653-662.
18. N. Hogan, "Guest Editorial: Rehabilitation Applications of Robotic Technology", Journal of Rehabilitation Research and Development, Vol. 37, No. 6, Nov/Dec 2000, pp. ix-x.
19. H.F. Schulte, Jr., "The Characteristics of the McKibben Artificial Muscle", in The Application of External Power in Prosthetics and Orthotics, Publication 874 National Academy of Sciences – National Research Council, Washington, D.C., 1961, pp.94-115.

20. V.L. Nickel, J. Perry, A.L. Garrett, "Development of Useful Function in the Severely Paralyzed Hand", Journal of Bone and Joint SurgeryVol 45-A, No. 5, July 1963, pp. 933-952.
21. C-P. Chou, B. Hannaford, "Measurement and Modeling of McKibben Pneumatic Artificial Muscles", IEEE Transactions on Robotics and Automation, Vol. 12, No. 1, Feb. 1996, pp. 90-102.
22. G. K. Klute, B. Hannaford, "Modeling Pneumatic McKibben Artificial Muscle Actuators: Approaches and Experimental Results", ASME Journal of Dynamic Systems, Measurement, and Control, Nov. 1998.
23. G.K. Klute, J.M. Czeniecki, B. Hannaford, "McKibben Artificial Muscles: Pneumatic Actuators with Biomechanical Intelligence", IEEE/ASME 1999, International Conference on Advanced Intelligent Mechantronics (AIM '99), Sept 19-22, 1999.
24. C-P Chou, B. Hannaford, "Static and Dynamic Characteristics of McKibben Pneumatic Artificial Muscles", 1994.
25. G.K. Klute, B. Hannaford, "Fatigue Characteristics of McKibben Artificial Muscle Actuators", University of Washington.
26. G. Francisco, J. Chae, H. Chawla, S. Kirshblum, R. Zorowitz, G. Lewis, S. Pang, "Electromyogram-Triggered Neuromuscular Stimulation for Improving the Arm Function of Acute Stroke Survivors: A Randomized Pilot Study", Arch Phys Med Rehabil, Vol. 79, May 1998, pp. 570-575.
27. J. Cauraugh, K. Light, S. Kim, M. Thigpen, A. Behrman, "Chronic Motor Dysfunction After Stroke", Recovering Wrist and Finger Extensiion by Electromyography-Triggered Neuromuscular Stimulation", Stroke, 2000, Vol. 31, pp 1360-1364.
28. G.H. Kraft, S.S. Fitts, M.C. Hammond, "Techniques to Improve Function of the Arm and Hand in Chronic Hemiplegia", Arch Phys Med Rehabil, Vol. 73, March 1992, pp. 220-227.
29. M. Glanz , S. Klawansky, W. Stason, C. Berkey, T. Chalmers, "Functional Electrostimulation in Poststroke Rehabilitation: A meta-analysis of the Randomized controlled Trials", Archives of Physical Medicine and Rehabilitation, 1996 Vol.77, pp.549-553.
30. J.D. Moreland, M. Thomson, A.R. Fuoco, "Electromyographic Biofeedback to Improve Lower Extremity Function After Stroke: A Meta-Analysis", Arch Phys Med Rehabil, Vol 79, Feb. 1998, pp. 134-140.
31. S.L. Wolf, D.E. Lecraw, L.A. Barton, B.B. Jann, "Forced Use of Hemiplegic Upper Extremities to Reverse the Effect of Learned Nonuse Among Chronic Stroke and Head-Injured Patients", Experimental Neurology, Vol 104, 1989, pp. 125-132.
32. E. Taub, N.E. Miller, T.A. Novack, E.W. Cook, W.C. Fleming, C.S. Nepomuceno, J.S. Connell, J.E. Crago, "Technique to Improve Chronic Motor Deficit After Stroke", Arch Phys Med Rehabil, Vol. 74, April 1993, pp. 347-354.
33. http://www.shadow.org.uk
34. J. Chae, R. Hart, "Comparison of Discomfort Associated with Surface and Percutaneous Intramuscular Electrical Stimulation for Persons with Chronic Hemiplegia", Am J Phys Med Rehabil, 1998, Nov-Dec, Vol. 77 No. 6, pp. 516-22.
35. C.G. Ostendorf, S.L. Wolf, "The effect of forced use of upper extremity of a hemiplegic patient on changes in function: a single case design", Phys Ther 62:1022-1028, 1981.
36. S.L. Wolf, "Forced use of a paretic upper extremity may facilitate function in select chronic head injured patients," Research Forum 1:4-5, 1986.
37. Extremity Constraint-Induced Training Evaluation (EXCITE) trial, Steven L. Wolf, Ph.D., FAPTA, Principal Investigator, NCMRR,HD 37606.
38. S.L. Wolf, P.A. Catlin, M. Ellis, A. Link, B. Morgan, A. Piacentino, "Assessing the Wolf motor function test as an outcome measure for research with patients post-stroke", Stroke, 32:1635-39, 2001.

39. P.M. Duncan, SM Lai, "Stroke Recovery", Topics in Stroke Rehabilitation, Vol 4, No. 3, pp. 51-58, 1997.
40. *R. Herman, "The Myotactic Reflex", Brain, 93, 273-312, 1970.*

### *H. CONTRACTUAL ARRANGEMENTS*

Dr. Wolf is participating at no cost with the anticipation that this study will lead to a device that is supportive of the treatments being studied in the EXCITE trial.

The applicant organization and St. Joseph's Medical Center/ St. Joseph's Medical Center are prepared to establish in writing the required contractual agreements whereby the clinical institutions will provide physician and therapist services as described in this proposal. The cost of providing these services is included in the budget of this proposal.

### *I. CONSULTANTS*

An Advisory Board for the project will provide advice and guidance on clinical issues, engineering, and product development. The members of the Advisory Board are:

- Dr. Steven Wolf, Ph.D., Professor of Rehabilitation Medicine at Emory University. Dr. Wolf is the principal investigator of a randomized national clinical trial to explore the effect of forced use therapy on patients who have sustained a stroke. He will be advising on the treatment and evaluation protocols and provide general guidance on the treatment of stroke patients.
- Deborah Koeneman has a MS degree in Bioengineering from ASU. She has worked for the Food and Drug Administration in regulation of Medical Devices. She currently is Director of Regulatory Affairs for OrthoLogic Corporation. She will consult on clinical trial, regulatory, and quality assurance issues.
- Don Herring, an Assistant Professor of Industrial Design at ASU, will consult on human factors, industrial design, and attachment design.
- Cristobel Eblen, Ph D., Cris is a psychologist with experience in designing patient evaluation studies and questionnaires and performing statistical analyses.

EXHIBIT C

EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Center for Rehabilitation Medicine
Department of Rehabilitation Medicine

July 22, 2002

Mr. James B Koeneman, President
Kinetic Muscles, Inc.
1949 East Broadway Road
Suite D
Tempe, AZ 85282

Dear Jim:

I have read your revised SBIR proposal, "Development of a Massed Practice Stroke Therapy Device"(1 R43 HD41805-01A) regarding the application of your combined force feedback, EMG biofeedback, and pneumatic muscle instrumentation to facilitate improved movement and function in the wrists and digits of patients who have sustained a stroke but in whom movement initiation into extension exists. I believe you have responded admirably to the reviewers comments and that the decision to first field test your device using able-bodied individuals, is a wise one.

As you know, I have spent considerable time researching criteria for the use of EMG biofeedback applied to the upper extremities of patients after stroke. I have also done considerable work in the area of "forced use" or "constraint induced movement therapy" among stroke patients and currently am PI on the NIH funded EXCITE (EXtremity Constraint Induced Therapy Evaluation) national clinical trial. I will be more than honored to serve as a consultant to your project. I am very concerned that the potential to use multi-modal (muscle and force) physiological feedback be made optimal and researched with extreme vigor. I believe that your device will assist in the delivery of excellent product development and well-performed research. I am most impressed by your staff's commitment to this project.

Good luck with your efforts. Having read your proposal, I believe you have addressed all the reviewer comments comprehensively. If I can assist in any way during the final preparation of this proposal, please feel free to call upon me.

Steven L. Wolf

STEVEN L. WOLF, Ph.D., FAPTA, PT
Professor, Department of Rehabilitation Medicine
Professor of Geriatrics, Department of Medicine
Associate Professor, Department of Cell Biology
Director, Program in Restorative Neurology (PROREN)
Emory University School of Medicine

Emory University School of Medicine
1441 Clifton Road NE
Atlanta, Georgia 30322

Tel 404.712.5507
Fax 404.712.5895

**Barrow Neurological Institute®**
St. Joseph's Hospital and Medical Center

June 1, 2001

To whom it may concern:

This letter shall serve as a letter of support for the Small Business Innovation Research grant titled "Development of a Massed Practice Stroke Therapy Device." I am pleased to be asked to participate in the opportunity to engineer a device that may assist patients in applying the principles of massed practice in their stroke recovery.

As Director of Brain Injury Rehabilitation at Barrow Neurological Institute, I have the background to be able to participate in such research. I am looking forward to collaboration in this study.

Sincerely,

C Kwasnica MD

Christina Kwasnica M.D.
Attending Physiatrist
Barrow Neurological Institute
St. Joseph's Hospital & Medical Center
Phoenix, AZ 85013

EXHIBIT C

*Barrow Neurological Institute®*
St. Joseph's Hospital and Medical Center
CHW

350 West Thomas Road
Phoenix, AZ 85013
602 406 3000 Telephone

March 29, 2001

James B. Koneman, Ph.D.
1937 East Broadway Road
Tempe, AZ 85282-1701

Dear Dr. Koneman:

The research project "Development of a Massed Practice Stroke Therapy Device" as submitted by BTI Consultants has the full administrative support and approval of our institution.

Catholic Healthcare West Arizona, dba St. Joseph's Hospital and Medical Center, is familiar with federal subcontract policies. Upon negotiation of a NIH subcontract, our institution will fully comply with those policies if the grant is awarded to BTI Consultants.

Sincerely,

Toby L. Anchie, R.N., MAEd
Executive Director, Research & Development

EXHIBIT C

Principal Investigator/Program Director (Last, First, Middle): Koeneman, James, Bryant

## CHECKLIST

**TYPE OF APPLICATION** *(Check all that apply.)*

☐ NEW application. *(This application is being submitted to the PHS for the first time.)*

☒ ☐ _ SBIR Phase I ☐ SBIR Phase II: SBIR Phase I Grant No _ ☐ SBIR Fast Track

☐ STTR Phase I ☐ STTR Phase II: STTR Phase I Grant No. _ ☐ STTR Fast Track

☒ REVISION of application number: 1R43HD041805-01A1

*(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)*

☐ COMPETING CONTINUATION of grant number:

*(This application is to extend a funded grant beyond its current project period.)*

INVENTIONS AND PATENTS *(Competing continuation appl. and Phase II only)*

☐ No ☐ Previously reported

☐ Yes. If "Yes," ☐ Not previously reported

☐ SUPPLEMENT to grant number:

*(This application is for additional funds to supplement a currently funded grant.)*

☐ CHANGE of principal investigator/program director.

Name of former principal investigator/program director:

☐ FOREIGN application or significant foreign component.

**1. PROGRAM INCOME** ***(See Instructions.)***

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request If program income is anticipated, use the format below to reflect the amount and source(s).

| Budget Period | Anticipated Amount | Source(s) |
|---|---|---|
| | 0 | |

**2. ASSURANCES/CERTIFICATIONS** ***(See Instructions.)***

The following assurances/certifications are made and verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Descriptions of individual assurances/ certifications are provided in Section III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

•Human Subjects; •Research Using Human Embryonic Stem Cells• •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy• Vertebrate Animals• •Debarment and Suspension; •Drug- Free Workplace *(applicable to new [Type 1] or revised [Type 1] applications only)*; •Lobbying; •Non-Delinquency on Federal Debt; •Research Misconduct; •Civil Rights (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA and Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution Participation.

**3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS.** See specific instructions.

☐ DHHS Agreement dated: ☒ ☐ _ No Facilities And Administrative Costs Requested.

☐ DHHS Agreement being negotiated with Regional Office.

☐ No DHHS Agreement, but rate established with Date

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| a. Initial budget period: | Amount of base $ | | x Rate applied | | % = F&A costs | $ | |
| b. 02 year | Amount of base $ | | x Rate applied | | % = F&A costs | $ | |
| c. 03 year | Amount of base $ | | x Rate applied | | % = F&A costs | $ | |
| d. 04 year | Amount of base $ | | x Rate applied | | % = F&A costs | $ | |
| e. 05 year | Amount of base $ | | x Rate applied | | % = F&A costs | $ | |
| | | | | | TOTAL F&A Costs $ | | |

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.)*:

**4. SMOKE-FREE WORKPLACE** ☒ Yes ☐ No *(The response to this question has no impact on the review or funding of this application.)*

## Section E Human Subjects (addendum)

### *Inclusion Plans for Women, Minorities & Children*

The targeted enrollment in the Pilot Study is in the following table. Children less than 18 years of age are excluded because an immature nervous system may respond differently to this therapy than a mature one and the low number of young patients available for this short study. See Involvement of Human Subjects on p. 24.

## Targeted/Planned Enrollment Table

**This report format should NOT be used for data collection from study participants.**

**Study Title:** Pilot Study of Usability, Safety and Feasibility of Stroke Therapy Device

**Total Planned Enrollment:** 10

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| **Ethnic Category** | **Sex/Gender** | | |
| | **Females** | **Males** | **Total** |
| Hispanic or Latino | 1 | 0 | 1 |
| Not Hispanic or Latino | 6 | 3 | 9 |
| Ethnic Category Total of All Subjects* | 7 | 3 | 10 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 1 | 1 | 2 |
| White | 6 | 2 | 8 |
| Racial Categories: Total of All Subjects * | 7 | 3 | 10 |

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

### *Data & Safety Monitoring Plan*

Adverse events will be monitored during the clinical study to determine if there are any device-related adverse effects. As outlined on page 25 of this proposal, anticipated potential adverse device effects include overextension of the wrist and/or fingers, patient fatigue, and skin irritation under EMG electrodes. All anticipated adverse device effects will be reported to the Data Safety Monitoring Board (see p. 22) as they occur and a summary of all events will be supplied to the IRB and the NIH at the conclusion of the study.



Sent e-mail 7/30/02

An *unanticipated adverse device effect* is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Investigators will be required to submit reports of unanticipated adverse device effects KMI, NIH and the reviewing IRB as soon as possible and no later than 10 working days after the investigator first learns of the effect.

KMI will submit results of evaluations of unanticipated adverse device effects to the FDA, NIH, IRB, and participating investigators within 10 working days after receiving notice of effect.

*justments and then the final group comes in for the beginning of one week of treatment. At the end of the study, a Focus Group will be held to have interaction between the participant therapists and caregivers in evaluating the device and providing further suggestions. A report of the Focus Group will document the participant's opinions of usability and safety of the device. Concurrent with the participant evaluations, performance characterization of the device, update of the hazard analysis and adjustments to the firmware and displays will be made. A final report addressing the feasibility of the device, device changes suggested by the results, and protocol changes suggested for the Phase II study will be prepared. Assuming feasibility is demonstrated, an application for Phase II funding will be prepared for December 1, 2003, submission.*

Table I Gantt Chart

| ID | Task Name | Q2 '03 | | | Q3 '03 | | | Q4 '03 | |
|---|---|---|---|---|---|---|---|---|---|
| | | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov |
| 1 | Device Manufacture | | | | | | | | |
| 2 | Prepare Study Materials | | | | | | | | |
| 3 | Study Clinician In-Service | | | | | | | | |
| 4 | Patient Recruitment | | | | | | | | |
| 5 | Pilot Study | | | | | | | | |
| 6 | Focus Group | | | | | | | | |
| 7 | Data Analysis | | | | | | | | |
| 8 | Device Characteriation | | | | | | | | |
| 9 | Interactive Tx Protocol Dev | | | | | | | | |
| 10 | Final Report Preparation | | | | | | | | |
| 11 | Phase II Proposal Submittal | | | | | | | | |

*The* **deliverables** *of this Phase I study are: (1) a complete characterization of the device performance and hazard analysis, (2) refined displays, donning and doffing procedures and other device features that make the device user friendly, (3) the documented opinions of caregivers and clinicians as to usability, acceptance, and safety of the device.*

*The feasibility of using this device in a Phase II study involving stroke patients will be determined by the safety and usability conclusions.*

## E. HUMAN SUBJECTS

Involvement of Human Subjects: The purpose of the device under evaluation in this proposal is to facilitate the application of concentrated practice for stroke patients. Numerous studies, most notably by Taub and Wolf, have provided this therapy through one-on-one contact with physical therapists. In all of these studies there is no reason to believe that this intervention provides selective benefits (or limitations) based upon gender or racial attributes. In this study the gender and minority status will be recorded and reported for all participants. The numbers are so small that little meaningful statistical conclusions can be made although physiological and functional performance will be reported for these categories. Children less than 18 years of age are excluded because an immature nervous system may respond differently to this therapy than a mature one and the low number of young patients available for this short study.

Human Research Material: *Participants will be in two groups. Group I will be clinicians that have treated stroke patients for a minimum of three years. The identity of participants will be protected. Participants in this trial will receive codes to protect their identity throughout the study.*

Recruitment of subjects: *The clinician participants will be recruited by the two physical therapists that are familiar with this device (Kay Wing and Deborah Taylor). The caregivers of stroke patients will be recruited by Dr. Kwasnica, Kay Wing, and Deborah Taylor.*

Potential Risks: The physical risk involved with using this device is overextending a joint and causing soft tissue damage. *To control this risk the range of motion of the mechanism is limited to the physiological range of motion of a normal person. To protect against overload of spastic muscles or contractures, the amount of force the device can provide is limited. A panic button is provided that removes load and shuts the device down.* Another risk is fatiguing the patient and causing anxiety. The risks involved with use of EMG electrodes are skin irritation. A control on this risk is that the participant has the right to drop out of the study at any time.

Minimization of Risk: The risk of overstretching a joint is controlled in several ways. There is a physical stop incorporated in the device that prevents wrist extension over 60°degrees of extension. If the wrist is stopped by an obstruction, the force is limited by the low stiffness of the air muscle actuator. Also, if the torque measured by the extension bar exceeds 8 newton meters (the resistive torque of the finger and wrist flexors), the air is exhausted and the device shut down. A panic button is also provided for easy access by the unaffected hand that will also exhaust the air muscle and shut the device down if the patient is feeling any discomfort, fatigue or anxiety.

Reasonableness of Risk: As noted above, effective means of controlling the risks are designed into the device. When one realizes that the eventual potential benefit to stroke patients can be substantially enhanced function in real world activities and improved quality of life beyond that achieved during the early rehabilitation interval, the risks are not significant.

FDA Approval: It is our opinion that this device is not a significant risk device and that only IRB approval is required. We will submit the protocol, a description of the device, a patient consent form, and an evaluation of the hazards involved in use of the device and how we are controlling these hazards to the IRB.

## F. VERTEBRATE ANIMALS

Not applicable.

## G. LITERATURE CITED

1. H.I. Krebs, B.T. Volpe, M.L. Aisen, N. Hogan, "Increasing Productivity and Quality of Care: Robot-aided Neuro-rehabilitation", Journal of Rehabilitation Research and Development, Vol. 37, No. 6, Nov/Dec, 2000, PP 630-652.

EXHIBIT C

Principal Investigator/Program Director (Last, first, middle):

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD**
**DIRECT COSTS ONLY**

FROM 7/01/04 THROUGH 6/30/05

| PERSONNEL *(Applicant organization only)* | | | | | DOLLAR AMOUNT REQUESTED *(omit cents)* | | |
|---|---|---|---|---|---|---|---|
| NAME | ROLE ON PROJECT | TYPE APPT *(months)* | % EFFORT ON PROJ. | INST. BASE SALARY | SALARY REQUESTED | FRINGE BENEFITS | TOTAL |
| Richard Herman, MD | Principal Investigator | 12 | 20.0 | 100,000 | 20,000 | 4,800 | 24,800 |
| Vassia Roulia | Res Monitor | 12 | 30.0 | 55,000 | 16,500 | 3,960 | 20,460 |
| Therapist | Evaluator | 12 | 50.0 | 61,167 | 33,584 | 8,060 | 41,644 |
| Res. Coordinator | Clin. Res Coordinator | 12 | 50.0 | 73,840 | 36,920 | 8,861 | 45,781 |
| | | | 0.0 | 0 | 0 | 0 | 0 |
| | | | | | | | |
| | | | | | | | |
| **SUBTOTALS** → | | | | | 87,004 | 20,881 | 107,884 |

| | | |
|---|---|---|
| CONSULTANT COSTS | | 0 |
| EQUIPMENT *(itemize)* | | 0 |
| SUPPLIES *(itemize by category)* | | 0 |
| TRAVEL | | |
| Nat'l Stroke Mtg | | 1,500 |
| PATIENT CARE COSTS | INPATIENT | |
| | OUTPATIENT | 0 |
| ALTERATIONS AND RENOVATIONS *(itemize by category)* | | |
| OTHER EXPENSES *(itemize by category)* | | |
| **SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** | | $109,384 |
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS | |
| | FACILITIES AND ADMINISTRATIVE COSTS | 0 |
| **TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** *(Item 7a, Face Page)* → | | $109,384 |
| **SBIR/STTR Only: FEE REQUESTED** | | |

EXHIBIT C

Form Approved Through 05/2004 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

# Grant Application

*Do not exceed character length restrictions indicated.*

**LEAVE BLANK—FOR PHS USE ONLY**

| Type | Activity | Number |
|---|---|---|
| Review Group | | Formerly |
| Council/Board (Month, Year) | | Date Received |

1. TITLE OF PROJECT *(Do not exceed 56 characters, including spaces and punctuation.)*

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
*(If "Yes," state number and title)*
Number: Title:

| 3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR | New Investigator ☐ No ☐ Yes |
|---|---|
| 3a NAME *(Last, first, middle)* | 3b. DEGREE(S) |
| 3c. POSITION TITLE | 3d. MAILING ADDRESS *(Street, city, state, zip code)* |
| 3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT | |
| 3f. MAJOR SUBDIVISION | |
| 3g. TELEPHONE AND FAX *(Area code, number and extension)*<br>TEL: FAX: | E-MAIL ADDRESS: |

| 4. HUMAN SUBJECTS RESEARCH | 4a. Research Exempt ☐ No ☐ Yes<br>If "Yes," Exemption No. | | 5. VERTEBRATE ANIMALS ☐ No ☐ Yes | |
|---|---|---|---|---|
| ☐ No<br>☐ Yes | 4b. Human Subjects Assurance No. | 4c. NIH-defined Phase III Clinical Trial<br>☐ No ☐ Yes | 5a. If "Yes," IACUC approval Date | 5b. Animal welfare assurance no. |

| 6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)* | | 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD | | 8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT | |
|---|---|---|---|---|---|
| From | Through | 7a. Direct Costs ($) | 7b. Total Costs ($) | 8a. Direct Costs ($) | 8b. Total Costs ($) |
| | | | | | |

| 9. APPLICANT ORGANIZATION | 10. TYPE OF ORGANIZATION |
|---|---|
| Name<br>Address | Public: → ☐ Federal ☐ State ☐ Local<br>Private: → ☐ Private Nonprofit<br>For-profit: → ☐ General ☐ Small Business<br>☐ Woman-owned ☐ Socially and Economically Disadvantaged |
| | 11. ENTITY IDENTIFICATION NUMBER<br>DUNS NO. |
| Institutional Profile File Number (if known) | Congressional District |

| 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE | 13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION |
|---|---|
| Name<br>Title<br>Address | Name<br>Title<br>Address |
| Tel: FAX:<br>E-Mail: | Tel: FAX:<br>E-Mail: |

| 14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE. I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. | SIGNATURE OF PI/PD NAMED IN 3a<br>*(In ink. "Per" signature not acceptable.)* | DATE |
|---|---|---|
| 15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE. I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. | SIGNATURE OF OFFICIAL NAMED IN 13.<br>*(In ink. "Per" signature not acceptable.)* | DATE |

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD**
**DIRECT COSTS ONLY**

FROM 7/01/04 THROUGH 6/30/05

| PERSONNEL *(Applicant organization only)* | | | | | DOLLAR AMOUNT REQUESTED *(omit cents)* | | |
|---|---|---|---|---|---|---|---|
| NAME | ROLE ON PROJECT | TYPE APPT. *(months)* | % EFFORT ON PROJ. | INST. BASE SALARY | SALARY REQUESTED | FRINGE BENEFITS | TOTAL |
| James Koeneman | Principal Investigator | 12 | 30.0 | 120,000 | 36,000 | 8,460 | 44,460 |
| Edward Koeneman | Engineering | 12 | 30.0 | 100,000 | 30,000 | 6,900 | 36,900 |
| Robert Schultz | Indust Des. | 12 | 30.0 | 38,000 | 11,400 | 2,622 | 14,022 |
| Pat Jacobson | Ops Mfg | 12 | 20.0 | 80,000 | 16,000 | 3,680 | 19,680 |
| TBN | ASU Intern | 12 | 50.0 | 30,000 | 15,000 | 0 | 15,000 |
| | | | | | | | |
| | | | | | | | |
| **SUBTOTALS** → | | | | | 72,400 | 13,202 | 85,602 |

| | | |
|---|---|---|
| CONSULTANT COSTS | | |
| Statitician | | 1,500 |
| EQUIPMENT *(Itemize)* | | |
| 20 devices @ 3500, Dell650 Workstation 1800 | | 71,800 |
| SUPPLIES *(Itemize by category)* | | |
| Software licenses, upgrades $1000<br>Electronics disks, cartridges $500<br>Electrodes & Supplies $500<br>Lab Supplies $2500 | | 4,500 |
| TRAVEL | | |
| Nat'l Stroke Mtg | | 1,500 |
| PATIENT CARE COSTS | INPATIENT | |
| | OUTPATIENT | 4,700 |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)* | | |
| OTHER EXPENSES *(Itemize by category)* | | |
| IRB Charges $2200 | | 2,200 |
| **SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** | | $171,802 |
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS | |
| | FACILITIES AND ADMINISTRATIVE COSTS 109K * 60% | 164,888 |
| **TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** *(Item 7a, Face Page)* → | | $ 323,610 |
| **SBIR/STTR Only: FEE REQUESTED** 7% | | 21,168 |

EXHIBIT C

## Facilities and Administrative (F&A) Costs

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS agency cost advisory office. If the applicant organization is in the process of initially developing or renegotiating a rate, or has established a rate with another Federal agency, it should, immediately upon notification that an award will be made, develop a tentative F&A cost rate proposal This is to be based on its most recently completed fiscal year in accordance with the principles set forth in the pertinent DHHS Guide for Establishing Indirect Cost Rates, and submitted to the appropriate DHHS Regional Office or PHS agency cost advisory office. F&A costs will NOT be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

# EXHIBIT C

**Personnel**

| Name | Role | Appt type | %Effort | Inst Sal. | Requested | Fringe | Subtotal | Totals |
|---|---|---|---|---|---|---|---|---|
| Richard Herman, MD | PI | 12 | 20 | 100.000 | 20,000 | 4,800 | 24,800 | |
| Vassia Rovira | Res Monitor | 12 | 30 | 55.000 | 16,503 | 3,960 | 20,463 | |
| Therapist | Evaluator | 12 | 50 | 67.167 | 33,584 | 8,060 | 41,644 | |
| Res Coordinator | Clinical Res Coor | 12 | 50 | 73.840 | 36,920 | 8,861 | 45,781 | |
| Evaluator | WMFT/adv/MRI | 12 | 0 | 30.000 | 0 | 0 | 0 | |
| Recruiter/Trainer | Rec/Train | 12 | 0 | 35.000 | 0 | 0 | 0 | |
| Kay Wing | Consult | 12 | 0 | 60.000 | 0 | 0 | 0 | |
| | Consult | 12 | 0 | 80.000 | 0 | 0 | 0 | |
| ***Personnel subtotal*** | | | | | ***87,004*** | ***20,881*** | ***107,884*** | ***107,884*** |
| | | | | | Fringe % GT | 0.240 | | |